What the data is telling us: the first 30 days need to be safer after any carotid repair, but how?

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Disclosure

Speaker name:

...............CARLO SETACCI .................

I have the following potential conflicts of interest to report:

☐ Consulting

☐ Employment in industry

☐ Shareholder in a healthcare company

☐ Owner of a healthcare company

☐ Other(s)

☒ I do not have any potential conflict of interest
CEA Vs CAS Trials: Current Evidence

Vs.
CONCLUSION

For every 1000 patients opting for stenting rather than endarterectomy:

19 more patients would have strokes,
3 more patients would be dead

10 fewer would have MIs

Meta-analysis of RCTs – updated 2011

As an endovascular oriented vascular surgeon
I believe in the Renaissance of CAS

WHY?
Long term CREST results:
Results at 4 year

The only difference is here!!
Renaissance of CAS

Room for periprocedural improvement

Freedom of MANE

Per-procedural

Post-procedural

Long term → OK!

Timeline (days)
We need better protection against SMALL emboli

| Per protocol                  | CAS  
 N = 1,131 | CEA  
 N = 1,176 | Difference | Unadjusted  
p-value* |
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>All Death, Stroke, or MI</td>
<td>5.8% (65)</td>
<td>5.1% (60)</td>
<td>0.7%</td>
<td>0.5200</td>
</tr>
<tr>
<td>Death</td>
<td>0.53% (6)</td>
<td>0.26% (3)</td>
<td>0.27%</td>
<td>0.3335</td>
</tr>
<tr>
<td>Any Stroke</td>
<td>4.1% (46)</td>
<td>1.9% (22)</td>
<td>2.2%</td>
<td>0.0019</td>
</tr>
<tr>
<td>Major Stroke</td>
<td>0.9% (10)</td>
<td>0.4% (5)</td>
<td>0.5%</td>
<td>0.2005</td>
</tr>
<tr>
<td>Minor Stroke</td>
<td>3.2% (36)</td>
<td>1.5% (18)</td>
<td>1.7%</td>
<td>0.0088</td>
</tr>
<tr>
<td>MI</td>
<td>2.0% (22)</td>
<td>3.4% (40)</td>
<td>-1.5%</td>
<td>0.0387</td>
</tr>
</tbody>
</table>

Besides:
  • Operator experience
  • Patient selection
  • Lesion selection

...we need a...

**Scaffolding Stent** to provide better protection against **SMALL** and **LATE** embolisation
Significant reduction in the incidence of new cerebral ischemic lesions (45.2% vs. 87.1%, \( p < 0.001 \)).

- number (\( p < 0.0001 \))
- volume (\( p < 0.0001 \))

of new cerebral ischemic reduced by proximal balloon occlusion.

(J Am Coll Cardiol 2012;59:1383–9)
WHICH STENT?

Wallstent (BSCI)  
Adapt (BSCI)  
Closed cell

Precise (Cordis)  
Acculink (Guidant)  
Open cell
Comparison of post-procedural event rates by cell types

- Sample 3179 Pts -

All Pts Sympt Pts Asympt Pts
Closed cell 1,3 1,3 1,3
Open cell 3,4 6,3 1,4

P = ns

P<.001


Does free cell area influence the outcome in carotid artery stenting?

Eur J Vasc Endovasc Surg. 2007; 33: 135-41.

Italian- Belgium Registry
EJVES 2007
**Closed vs Open cell in RCT**

Jansen et al. Stroke 2009

![Graph showing SPACE vs CEA/CAS](image)

**Table:**

<table>
<thead>
<tr>
<th>Stent</th>
<th>Acculink</th>
<th>Precise</th>
<th>Wallstent</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients</td>
<td>92</td>
<td>35</td>
<td>436</td>
</tr>
<tr>
<td>Pat. with OE</td>
<td>9</td>
<td>5</td>
<td>24</td>
</tr>
<tr>
<td>OE rate (95% CI)</td>
<td>9.8% (4.6–17.8%)</td>
<td>14.3% (4.8–30.3%)</td>
<td>5.5% (3.6–8.1%)</td>
</tr>
<tr>
<td>Combined OE rate</td>
<td>11.0% (6.2–17.8%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Note:**
- Open cell / large free cell area
- Closed cell

**OR 2.13 [1.07-3.76]**
We need better protection against SMALL emboli.
We need better protection against SMALL & LATE emboli

Symptomatic group “late” SDR 1,9%


Does free cell area influence the outcome in carotid artery stenting?

Eur J Vasc Endovasc Surg. 2007; 33: 135-41.
Ideal stent

- Low profile
- High trackability & flexibility
- Complete plaque coverage
- Perfect vessel apposition

Answer by OCT
Optical Coherence Tomography is an intravascular high-resolution (10 micron) imaging technology that employs near-infrared light.
Safety and Feasibility of Intravascular Optical Coherence Tomography Using a Nonocclusive Technique to Evaluate Carotid Plaques Before and After Stent Deployment

Carlo Setacci, MD; Gianmarco de Donato, MD; Francesco Setacci, MD; Giuseppe Galzerano, MD; Pasqualino Sirignano, MD; Alessandro Cappelli, MD; and Giancarlo Palasciano, MD

Department of Surgery, Vascular and Endovascular Surgery Unit, University of Siena, Italy.
**Objectives**

To evaluate the rate of:

- **stent malapposition**
- plaque prolapse
- fibrous cap rupture

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**Optical Coherence Tomography After Carotid Stenting: Rate of Stent Malapposition, Plaque Prolapse and Fibrous Cap Rupture According to Stent Design.** *Eur J Vasc Endovasc Surg 2013;45:579-87*
Objectives

To evaluate the rate of:

- stent malapposition
- plaque prolapse
- fibrous cap rupture

Design

Prospective single center study


OPTICAL COHERENCE TOMOGRAPHY AFTER CAROTID STENTING: RATE OF STENT MALAPPOSITION, PLAQUE PROLAPSE AND FIBROUS CAP RUPTURE ACCORDING TO STENT DESIGN. Eur J Vasc Endovasc Surg 2013;45:579-87
**Objectives**

To evaluate the rate of:
- stent malapposition
- plaque prolapse
- *fibrous cap rupture*

**Design**

Prospective single center study


OPTICAL COHERENCE TOMOGRAPHY AFTER CAROTID STENTING: RATE OF STENT MALAPPOSITION, PLAQUE PROLAPSE AND FIBROUS CAP RUPTURE ACCORDING TO STENT DESIGN. *Eur J Vasc Endovasc Surg 2013;45:579-87*
Objectives
To evaluate the rate of:
- stent malapposition
- plaque prolapse
- fibrous cap rupture
according to carotid stent design

Design
Prospective single center study

OPTICAL COHERENCE TOMOGRAPHY AFTER CAROTID STENTING: RATE OF STENT MALAPPOSITION, PLAQUE PROLAPSE AND FIBROUS CAP RUPTURE ACCORDING TO STENT DESIGN. . *Eur J Vasc Endovasc Surg* 2013;45:579-87
Ideal stent - OCT answer

- Stent malapposition is more frequent with closed cell stent
- Plaque prolapse is more common with open cell stents

We need new stent design
We need MESH-STENT
New carotid stent design

Terumo - Roadsaver

Gore – Mesh carotid stent

Inspire – C-Guard
Impact of new stent design

**Sustained embolic protection**
- Double layer micromesh nitinol design
- Smallest cell stent size preventing embolic release

**Lesion specific scaffolding:**
- Extremely high plaque coverage
- Superior in vessel flexibility
- Excellent wall apposition: the two mash layers enable a flexible scaffold

“P.Valdoni” Department of Surgery – Sapienza University of Rome
Impact of new stent design
Impact of new stent design
Italian registry _ Roadsaver

Torino: Dr. C. Rabbia Radiologist
Cotignola: Dr. A. Cremonesi Cardiologist
Siena: Prof. C. Setacci Vascular Surgeon

3 Italian Vascular Centers
Preliminary results

3 Centers

Cotignola  n = 51
Siena      n = 17
Torino    n = 9

77
Subgroup analysis_MR

- Magnetic Resonance evaluation of cerebral parenchyma before and 24 hours post-op

New lesions in 1 case @ 24 hrs (n=3 in the ipsilateral and n=2 in controlateral hemisphere)
Italian registry _ Roadsaver

Subgroup analysis _ OCT

No plaque prolaps at OCT
Preliminary results

30 days
0% stroke or deaths
0% postprocedural TIAs
Prospective international trial

CLEAR ROAD – participating centers

- PI: Dr. Bosiers, AZ Sint-Blasius, Dendermonde, Belgium

- Participating centers:
  - 5 Belgian centers
  - 4 German centers
  - 3 Italian centers
Prospective international trial

Sustained embolic protection device....

CLEAR ROAD TRIAL

- Physician-initiated, prospective, multicenter, carotid trial investigating the efficacy of endovascular treatment of carotid arterial disease with the multilayer RoadSaver stent on **100 subjects**

- Objective: to evaluate the clinical outcome (up to 1 year) of CAS with the RoadSaver stent in subjects at high risk for CEA.
CLEAR ROAD trial
Impact of new stent design

Inspire CGuard is based on a stent which is wrapped with an expandable, MicroNet (mesh). The net is made of a single knitted PET fiber, and it is attached only to the proximal and distal edges of the stent.
Impact of new stent design

ITALIAN REGISTRY IN VASCULAR SURGERY CENTRES
Registry Rationale

WE NEED SIMILAR OUTCOME OF CEA AND CAS WITHIN 30 DAYS
Iron Guard
Physician-initiated prospective Italian Registry of carotid stenting with the C-Guard mesh-stent.
Physician-initiated prospective Italian Registry of carotid stenting with the C-Guard mesh-stent: the IRON-Guard registry. Rationale and design.

Setacci C¹, Speziale F, de Donato G, Sirignano P, Setacci F, Capoccia L, Galzerano G, Mansour W.

Author information

Abstract
BACKGROUND: According to the World Health Organization, every year, 5 million peoples die for stroke and another 5 million are permanently disabled. Although there are many causes of acute stroke, a common treatable cause of acute stroke is atheromatous narrowing at the carotid bifurcation. Carotid endarterectomy is still the standard of care, even if carotid artery stenting (CAS) has become an effective, less invasive alternative. Unfortunately, CAS procedure is not yet perfect; regardless the use of an embolic protection device (EPD), percutaneous treatment has been correlated with a risk of cerebral ischemic events related to distal embolization.
OBJECTIVES
The objective of this clinical investigation is to evaluate the clinical outcome (up to 12 months) of treatment by means of stenting with the C-Guard (InspireMD) in subjects requiring carotid revascularization due to significant extra-cranial carotid artery stenosis.
CGuard™ embolic prevention stent
ENDPOINTS

6.1 Primary Endpoint
The primary endpoint of this study is the 30-day rate of major adverse events (MAE), defined as the cumulative incidence of any peri-procedural (≤ 30 days post-procedure) death, stroke or myocardial infarction (MI).

6.2 Secondary Endpoints
1. Late ipsilateral stroke (31 through 365 days)
2. System Technical Success
3. Device malfunctions.
4. Major Adverse Events (MAEs)
5. Serious device-related and procedure-related Adverse Events (SAEs) as defined per ISO 14155-1:2011.
6. Target Lesion Revascularization (TLR).
7. In-Stent Restenosis (ISR).
What the data is telling us: the first 30 days need to be safer after any carotid repair, but how?

We have to avoid an inappropriate approach to CAS related to:

1. Poor specific competence
2. Inadequate training
3. Inadequate materials
What the data is telling us: the first 30 days need to be safer after any carotid repair, but how?

Devastating sequelae:

1. Wrong patient selection and indication
2. Incapacity to manage complications
THANKS FOR THE ATTENTION